

DOCKET NO.: CELG-0422

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Jerome B. Zeldis, et al.

Confirmation No.: 8455

Application No.: 10/820,397

Group Art Unit: 1614

Filing Date: April 8, 2004

Examiner: Not Yet Assigned

For: **METHODS FOR TREATMENT OF COGNITIVE AND MENOPAUSAL  
DISORDERS WITH D-THREO METHYLPHENIDATE**

DATE OF DEPOSIT: *January 7, 2005*

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Dear Sir:

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

- ☒ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of

the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

- ☐ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.116 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

- ☐ Certification in Accordance with § 1.97(e) is attached; or
- ☐ The fee of **\$180.00** as set forth in § 1.17(p) is attached.

- ☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of **\$180.00** as set forth in § 1.17(p).

- ☒ Copies of reference numbers **100 – 115 and 129 - 142** listed on the attached Form PTO-1449 are enclosed herewith.

- ☒ Copies of reference numbers **116 - 128** on the attached Form PTO 1449 are not required to be submitted pursuant to 37 CFR § 1.98(a)(2)(i).

- ☐ Copies of references - are not being submitted because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application number \_\_\_\_\_, filed \_\_\_\_\_ for which a claim for priority under 35 U.S.C. § 120 has been made in the instant application.


- ☐ The relevance of those listed references which are not in the English language is as follows:

There are no listed references which are not in the English language.

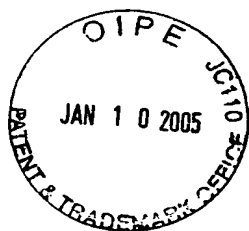
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<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office		Docket No. CELG-0422	Application No. 10/820,397
		Applicant Jerome B. Zeldis, et al.	
		Filing Date April 8, 2004	Group 1614
		Confirmation No. 8455	
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	100	Aoyama, T., et al., Gas chromatographic-mass spectrometric analysis of <i>threo</i> -methylphenidate enantiomers in plasma," <i>J. Chromatography</i> , <b>1989</b> , 494, 420-423	
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	103	Davies, H.M.L., et al., "Highly regio-, diastereo-, and enantioselective C – H insertions of methyl aryldiazoacetates into cyclic N-boc-protected amines, asymmetric synthesis of novel C <sub>2</sub> -symmetric amines and <i>threo</i> -methylphenidate," <i>J. Am. Chem. Soc.</i> , <b>1999</b> , 121, 6509-6510	
	104	Deutsch, H.M., et al., "Synthesis and pharmacology of potential cocaine antagonists. 2. Structure-activity relationship studies of aromatic ring-substituted methylphenidate analogs," <i>J. Med. Chem.</i> , <b>1996</b> , 39, 1201-1209	
	105	Hubbard, J.W., et al., "Enantioselective aspects of the disposition of <i>dl-threo</i> -methylphenidate after the administration of a sustained-release formulation to children with attention deficit-hyperactivity disorder," <i>J of Pharm. Sci.</i> , <b>1989</b> , 78(11), 944-947	
	106	Dirksen, S.J.H., et al., "A postmarketing clinical experience study of Metadata® CD," <i>Curr. Med. Res. And Opinion</i> , <b>2002</b> , 18(7), 371-380	
	107	Lim, H.K., "Enantiomeric resolution of <i>dl-threo</i> -methylphenidate, U.S.P. (Ritalin®), by high-performance liquid chromatography," <i>J. of Chromatography</i> , <b>1985</b> , 378-386	
	108	Matsumura, Y., et al., "A convenient method for synthesis of enantiomerically enriched methylphenidate from <i>N</i> -methoxycarbonylpiperidine," <i>Organic Letters</i> , <b>1999</b> , 1(2), 175-178	
	109	Naito, T., et al., "Rearrangement of sulfonamide derivatives. V. Syntheses of methyl $\alpha$ -phenyl-2- and 4-piperidineacetate," <i>Chem. Pharm. Bull.</i> , <b>1964</b> , 12(5), 588-590	
	110	Panizzon, L., "Preparation of pyridyl- and piperidylarylacetonitriles and some derivatives.," <i>Helvetica Chimica Acta</i> , <b>1944</b> , 27, 1748-1756	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	

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<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	111	Prashad, M., et al., "Enzymatic resolution of ( $\pm$ )- <i>threo</i> -methylphenidate," <i>Tetrahedron: Asymmetry</i> , <b>1998</b> , 9, 2133-2136	
	112	Prashad, M., et al., "Enantioselective synthesis of (2 <i>S</i> ,2' <i>R</i> )- <i>erythro</i> -methylphenidate," <i>Tetrahedron: Asymmetry</i> , <b>1999</b> , 10, 3479-3482	
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<b>U. S. PATENT DOCUMENTS</b>							
<b>Examiner Initial</b>		<b>Document No.</b>	<b>Date</b>	<b>Name</b>	<b>Class</b>	<b>Subclass</b>	
	<b>116</b>	5,773,478	06/30/98	Richards, et al.	514	649	
	<b>117</b>	6,031,124	02/29/00	Fox, et al.	560	37	
	<b>118</b>	6,113,879	09/05/00	Richards, et al.	424	9.1	
	<b>119</b>	6,121,453	09/19/00	Zavareh	546	238	
	<b>120</b>	6,242,464 B1	06/05/01	Harris, et al.	514	317	
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	<b>128</b>	2003/0105134 A1	06/05/03	Harris, et al.	514	317	
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<b>FOREIGN PATENT DOCUMENTS</b>							
Examiner Initial		Document No.	Date	Country	Translation		
					YES	NO	
	129	WO 97/27176	07/31/97	PCT			
	130	WO 97/28124	08/07/97	PCT			
	131	WO 97/32851	09/12/97	PCT			
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